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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/590,060	06/08/2000	John Edward Pfeifer	PFE-004	1011
7	590 05/22/2003			
David P Gordon Esquire			EXAMINER	
65 Woods End Stamford, CT			ROSENBERGER, RICHARD A	
			ART UNIT	PAPER NUMBER
			2877	
		DATE MAILED: 05/22/2003		

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application N .	Applicant(s)			
Office Action Summary		09/590,060	PFEIFER ET AL.			
		Examiner	Art Unit			
		Richard A Rosenberger	2877			
	The MAILING DATE of this communication appears on the cov r sheet with the correspond nce address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status						
1)⊠	Responsive to communication(s) filed on 22 A	A <i>pril 2003</i> .				
2a) □	This action is <b>FINAL</b> . 2b)⊠ Thi	is action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) 🖾	Claim(s) $\underline{1-4,6-15}$ and $\underline{17-26}$ is/are pending in	the application.				
4a) Of the above claim(s) is/are withdrawn from consideration.						
5)⊠	5)⊠ Claim(s) <u>15 and 17-22</u> is/are allowed.					
6)⊠ Claim(s) <u>1-4, 6-14, and 23-26</u> is/are rejected.						
7)	Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or election requirement.  Application Papers						
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11) 🔲	The proposed drawing correction filed on	_is: a)□ approved b)□ disappro	oved by the Examiner.			
If approved, corrected drawings are required in reply to this Office action.						
12)☐ The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
a) ☐ The translation of the foreign language provisional application has been received.  15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachment(s)						
1) Notic	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal I	y (PTO-413) Paper No(s) Patent Application (PTO-152)			

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1. The amendment after final filed 22 April 2003 has been considered. Because of the change to claim 1 and the arguments accompanying the proposed changes, the amendment will be entered, the finality of the rejection mailed 9 December 2003 is withdrawn, and a new grounds of rejection entered as below. The delay in the inclusion of the Rybak reference is regretted. In preparing this action, it was discovered that instant claim 6 was dependent from cancelled claim 5; the delay in noting this is regretted.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is dependent form cancelled claim 5, and is thus incomplete.

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to

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which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-4, 6-14 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tamura et al (US 6,306,577) and Rybak (US 5,013,155), taken together, and in view of the acknowledged prior art of the instant specification.

Tamura shows that it is known in the art to determine the rate at which some characteristic which can be measured by an optical test changes by determining the time which is required for the optical measurement to change from one level to another. The system of Tamura is an optical measurement (column 3, line 27-29; column 7, lines 30-34), which, as well known in the art, can be routinely measured by means of a system with a light source and a detector which send light to and receives light from the sample. The reference specifically mentions that the measurement can be "transmitted light intensity" (column 1, line 27; column 2, line 52), which at least clearly suggests having the light source and detector positioned opposite each other relative to the sample.

The instant specification notes that it is known to use ampules to hold the sample in tests of the sort of interest in the instant claims; see the discussion of the prior art on pages 2 through 4 of the instant specification, which discusses the prior use of such ampules. The use of ampules for such a test would have been obvious because, as discussed in the instant specification, ampoules are known and are used in the prior art to hold the samples is similar tests.

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The Tamura et al reference does not contain teaching related to the manner in which the light is passed through the sample being tested, in particular it does not teach directing the light axially though the receptacle holding the ampule. Rybak shows a known system for measuring the transmitted light intensity in which an ampule (6, called a "vial" in the Rybak reference) is placed into a receptacle (4) within a housing, with a light source (LEDs 22, 24) which transmits light axially through the receptacle (4), and thus the ampule (vial 6), and has a detector (18) which detects at least some of the light transmitted through the receptacle to measure the transmitted light intensity.

It would have been obvious to use the known transmitted light intensity measuring system of Tamura et al because it is a known system for making the sort of light transmission measurements taught as being made by Tamura, and because Rybak teaches that the axial transmission of light through the ampule (or vial) has the benefit of providing a longer pathlength (column 1, lines 60-63: "Preferably, the optical path is aligned with the longitudinal axis of the vial so that the path length of the beam in the sample is as long as possible").

The second threshold level is inherently "a predetermined percentage" of the first, any two thresholds values can be presented as one being a predetermined percentage of the other. The use of such a system would be obvious to use with any measurement which changes over time.

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The reference teaches the use of calibration curves for different reactions be used to determine the amount of the substance being measured for (column 6, lines 59-60; column 8, lines 44-46; column 10, lines 65-66). Note that the reference teaches that the comparison with the calibration curve be done "automatically" (column 8, line 45); this requires that the curve be stored in computer memory in some manner, using a look-up table is a known manner of storing data in a computer memory and would have been obvious. It is notes that the instant specification does not disclose any details of how the "look-up table" is constructed or used, but rather assumes that look-up tables are so well known in the art that no disclosure beyond mere mention is required for adequate disclosure.

Duplicating the receptacle, light source and detector so that more than one sample can be measured at the same time would have been obvious because then a plurality of separate devices would not be needed.

The instant specification mentions that it is known in the prior art that with type of test being performed the ampoule should be maintained at a constant temperature (page 2, lines 8-10). Providing means to achieve this known end in the test of Tamura would have been obvious because it is known to be desirable.

Tamura et al teaches that the system may include a timer (column 7, line 46).

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Displaying information relating to the test and the operation of the device is in general known and would have been obvious because it aids the user in using the device and verifying that the device is functioning.

The instant specification mentions that the prior art uses a reagent that changes color; see page 2, lines 1-3. Choosing the light source to have a wavelength which is useful for making the desired measurement would have been obvious because that is the wavelength of light that is useful in making the measurement.

Rybak teaches that an LED can be used as the light source.

Rybak includes a cover (a door) for fro covering the receptacle after the sample ampule is placed into the instrument.

- 6. The art does not appear to teach "recording a maximum intensity of light transmitted through said ampoule by . . . identifying when said intensity of light transmitted through said ampoule stops increasing". Thus claims 15 is allowable, as are claims 17-22 dependent thereon.
- 7. The newly applied Rybak reference was cited on the IDS filed 18 September 2000, and is thus already of record. As it has now been applied, it has been cited on a Form PTO-892 by the examiner for convenience.

Goldstein (US 6,172,759) discusses the use of look-up tables as a known alternative to an algorithm (see column 2, lines 5-7: "... concentration information

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may be calculated by means of a look up table or may be calculated by an algorithm ...").

As mentioned in the remarks filed 22 April 2003, the possibility of a double 8. patenting rejection was mentioned in a telephone conversation with Applicant's Attorney on 21 April 2003. In that conversation, it was indicated that the examiner was aware of Applicant's earlier patent, and, based solely on the examiner's recollection of that patent, and without the patent or the claims of that patent in front of him, mentioned that should the argued limitation of transmitting the light axially through the sample be found allowable, the possibility of a double patenting rejection would have to be considered, as the patent claims, as recalled by the examiner at that time, are directed to a particular arrangement for accomplishing this. The examiner did not intend to be understood as stating such a rejection would be proper or would be made; it such an understanding was communicated apologies are made. The examiner intended only to be understood that the review of the instant claims relative to the patent claims would need to be made based upon the recollection of the examiner of the patent claims. The instant claims and the claims of the patent have been reviewed together, and there appears to be no double patenting rejection at this time. If the instant claims are in the future amended to include additional limitations concerning the details of the disclosed illumination arrangment, this question may need to be revisited.

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9. Papers related to this application may be submitted to Group 2800 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (15 November 1989). The fax number is (703) 308-7722.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. A. Rosenberger whose telephone number is (703) 308-4804. The examiner's normal work schedule is 8:00 to 4:30 eastern time, Monday through Friday.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0956.

R. A. Rosenberger 8 May 2003 Richard A. Rosenberger Primary Examiner